

26 July 2010

510(k) Summary

Model 9100 Family Vital Signs Monitor

Contact: Alex Kaplan
Director QA & RA
Criticare Systems, Inc.
20925 Crossroads Circle
Waukesha, WI 53186 USA
262-798-8282 Voice
262-798-8290 FAX

SEP 1 2010

Trade Name: 9100 Family Vital Signs Monitor

Common Name: Vital Signs Monitor

Classification Name: ST Segment Monitor with Alarm (MLD); Physiological Monitor (with Arrhythmia Detection or Alarms) (MHX) {CFR 870.1025}

Substantial Equivalence is claimed to : 8100/8500 Vital Signs Monitor (K012059). 8100 w/Arrhythmia & ST Analysis Vital Signs Monitor (K030613). 9100 Vital Signs Monitor (K091050).

Device Description:

The 9100 monitor measures and displays real time physiological data of the patient, including a graphical plethysmogram and numerical data. The 9100 is a modular system and can be used to monitor one or more of the following parameters: ECG, Noninvasive BP (NIBP), Invasive BP, Temperature, Respiratory Gases, Anesthetic Agent Gases and SpO₂. Arrhythmia and ST Segment analysis of the ECG waveforms is also offered. For all these vital parameters, the 9100 will be capable of limit alarms and alerts, printing of strip chart recordings and storing trends for retrospective review.

Comparison with predicate device:

Criticare Systems Inc. has developed and distributed physiological monitoring devices worldwide since its inception in 1984. The 9100 monitor utilizes existing core technologies from the predicate 8100 monitor for patient monitoring of ECG, Noninvasive BP (NIBP), Invasive BP, Temperature, Respiratory Gases, Anesthetic Agent Gases and SpO₂. The patient data collected by the 9100 monitor is displayed for the user on a graphic LCD equivalent to the predicate device. Key panels and a touchscreen provide a user interface equivalent to the predicate device. The packaging design of the

9100 monitor is molded plastic and allows for it to be either a stationary monitor or to be used during patient translocation within the healthcare facility, as did the predicate 8100.

Determination of Substantial Equivalence:

The 9100 monitor performance for each monitoring modality has been confirmed to be equivalent to the predicate device. Additionally, the 9100 complies with applicable safety and performance standards (detailed below) for each monitoring modality and verification of compliance has been completed. The patient monitoring technologies present in the 9100 monitor have been in clinical use for at least six years in the 8100 monitor and its predicates. CSI's field experience with these modalities in the predicate devices has been satisfactory. This combination of equivalence testing, applicable objective standards compliance and field experience substantiates a high level of confidence in the safety and efficacy of the 9100 monitor.

Therefore, the 9100 monitor is substantially equivalent to the predicate devices.

Compliance to standards and regulations:

The 9100 Vital Signs Monitor complies with the following national and international standards:

Safety

IEC 60601-1 Medical Electrical Safety
IEC 60601-1-2 EMC Compliance
IEC 60601-1-8 Alarms
IEC 60601-2-49 Multi-parameter Monitor Safety
ISO 10993-5,10-11 Biocompatibility

Performance

IEC 60601-2-30 NIBP Safety
EN 1060-1 NIBP Performance
EN 1060-3 NIBP Performance
AAMI SP-10 NIBP Performance
ISO 9919 Oximetry Performance
IEC 60601-2-27 ECG Safety
AAMI EC-13 Basic ECG Performance
AAMI EC-57 Performance of Cardiac Rhythm and ST Segment Measurement Algorithms
IEC 60601-2-34 Invasive Blood Pressure Safety
ISO 21647 Gas Monitor Performance
EN 12470-4 Temperature Performance



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Criticare Systems, Inc.
c/o Mr. Alex Kaplan
Director QA & RA
20925 Crossroads Circle
Waukesha, WI 53186

Re: K101602
Trade/Device Name: 9100 Family Vital Signs Monitor
Regulatory Number: 21 CFR 870.1025
Regulation Name: ST Segment Monitor with Alarm
Regulatory Class: II (two)
Product Code: MLD, MHX
Dated: June 30, 2010
Received: August 2, 2010

Dear Mr. Kaplan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



B Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

SEP 1 2010

510(k) Number (if known): K101602

Device Name: 9100 Family Vital Signs Monitor

Indications For Use:

This system is intended to monitor physiological parameters of patients within any healthcare environment. The user, responsible to interpret the monitored data made available, will be a professional health care provider. Physiological data, system alarms and patient data analysis will be available to the care provider from the monitor.

The monitored parameters are:

1. ECG
2. Noninvasive Blood Pressure (NIBP)
3. Invasive Blood Pressure (IBP)
4. Temperature
5. Respiratory Gases
6. Anesthetic Agent Gases
7. Respiratory Rate
8. Pulse Oximetry (SpO2)
9. Arrhythmia and ST Analysis of the ECG waveforms

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. J. Wilhelmsen

Division Sign-Off
Office of Device Evaluation
Evaluation and Safety
510(K) K101602